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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/805,220

03/22/2004

Kazunari Yamaguchi

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EXAMINER

CHEN, STACY BROWN

ART UNIT

PAPER NUMBER

1648

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<p align="center"><b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b></p>	<p><b>Application No.</b> 10/805,220</p>	<p><b>Applicant(s)</b> YAMAGUCHI ET AL.</p>	
	<p><b>Examiner</b> Stacy B. Chen</p>	<p><b>Art Unit</b> 1648</p>	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 26 February 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: 17,20-22 and 24-26.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.  
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_  
13. ☐ Other: \_\_\_\_\_.

Continuation of Item 7. Applicant's after-final amendment filed February 26, 2008 is acknowledged and entered.

The amendments to the claims overcome the objection regarding typographical errors.

The outstanding rejection of claims 17, 20-22 and 24-26 under 35 U.S.C. 112, first paragraph, for lacking written description, is maintained for reasons of record. Applicant argues that the specification discloses that IgM and IgG are correlated with detecting infection (paragraphs 51-54 of the patent application publication). The Office has considered this text. In response, this portion of the disclosure teaches that measurement of antibody is possible during infection. The disclosure does not say that the detection/measurement of antibody is indicative of an active infection. The Office maintains its position that the invention as filed is directed to a method for detecting an antibody, but not directly correlating the detection of antibody with an active infection (see page 4, lines 6-19).

The outstanding rejection of claims 17, 20-22 and 24-26 under 35 U.S.C. 112, first paragraph, for lack of enablement, is maintained for reasons of record. Applicant's arguments have been carefully considered but fail to persuade. Applicant argues that the claims do not refer to a particular stage of infection and that one of skill in the art would appreciate the well-established correlation between Ig production and BDV infection. In response to this argument, the Office reasonably interprets the claims as being directed to a method of detecting an active, on-going infection. It is known in the art, evidenced by Carbone, that viruses in general may or may not be present in subjects that have tested positive for anti-serum because some viruses are cleared while other persist, even with regard to BDV specifically (page 516, top of second column).

The outstanding rejection of claims 17, 20-22 and 24-26 over Yamaguchi in view of Watanabe, and further in view of Hatalski and Carbone is maintained for reasons of record. Applicant's arguments have been carefully considered but fail to persuade. Applicant argues that Yamaguchi teaches that the ECLIA test is insufficient to detect BDV antibodies, but should be combined with specific tests such as WB analysis. In response to this argument, the instant method claims are not limited to the recited steps because the claims use the open transitional language, "comprising".

/Stacy B. Chen/ 3-4-2008  
Primary Examiner, TC1600